CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

November 6, 2006

S. 2322
Consumer Assurance of Radiologic Excellence Act of 2006

As ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on September 20, 2006

SUMMARY

S. 2322 would amend the Public Health Service Act to require that the Secretary of Health and Human Services (HHS) establish national educational and credentialing standards for technologists who perform certain medical-imaging studies and procedures involving radiation therapy. The new federal standards would not pertain to equipment or to physicians, nurse practitioners, or physician assistants. All standards established under the bill would expire on September 30, 2016.

CBO estimates that implementing S. 2322 would result in additional discretionary spending of $2 million in 2007 and about $20 million over the 2007-2011 period, assuming the appropriation of the necessary amounts. CBO estimates that establishing national standards for technologists would have a negligible effect on direct spending. Enacting S. 2322 would not affect revenues.

S. 2322 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Although it would add new requirements for individuals who provide medical-imaging or radiation-therapy services in federally supported medical programs, S. 2322 would not preempt state laws that require individuals to be licensed or certified. Because the requirements of S. 2322 on individuals are only enforceable under government programs in which participation is voluntary, such requirements are considered conditions of participation in those programs.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 2322 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION[a]					
Estimated Authorization Level	2	3	5	5	6
Estimated Outlays	2	3	4	5	6

a. Enacting S. 2322 also could affect direct spending, but CBO expects that any such changes would be negligible.

BASIS OF ESTIMATE

Spending Subject to Appropriation

For this estimate, CBO assumes that S. 2322 will be enacted near the start of fiscal year 2007 and that the amounts necessary to implement the bill will be appropriated for each year.

National Standards for Selected Technologists Under S. 2322. S. 2322 would require the Secretary of HHS to establish educational and credentialing standards for technical personnel who perform, plan, evaluate, or verify dosing for medical imaging services and procedures involving radiation therapy. Medical imaging refers to any procedure used to visualize tissues, organs, or physiologic processes in humans for diagnosing illness or monitoring the progression of disease. Radiation therapy uses the emission of radiation for treating or preventing disease. (The new standards would not apply to certain routine dental procedures, and they would not pertain to equipment or to physicians, nurse practitioners, or physician assistants.)

S. 2322 also would require the Secretary to certify qualified entities as approved bodies for administering standards and accrediting the various ways a technologist could demonstrate compliance. All of the standards established under this legislation would expire on September 30, 2016.

Enforcement Authority. S. 2322 would require the Secretary to ensure that individuals, prior to performing or planning specified services, demonstrate compliance with the new standards. The bill would require all HHS programs that perform or pay for medical imaging services or radiation therapy to comply with such standards. It also would give the Secretary discretion to withhold payment by HHS programs for services furnished by technologists who are not certified.

Other Provisions. The bill would authorize the Secretary to develop alternative standards for rural areas or other underserved areas if necessary to assure access to quality health care. It would also require the Agency for Healthcare Research and Quality to conduct a study on the effect of the new federal standards on diagnostic accuracy, patient safety, and the availability and cost of services.

Administrative Costs to Implement S. 2322. S. 2322 does not specify which agency within HHS would administer the new standards. CBO assumes that the Food and Drug Administration (FDA) would coordinate with the Centers for Medicare & Medicaid Services (CMS) and the Health Services and Resources Administration to implement the bill. Given the uncertainty surrounding how the Secretary would develop and enforce the new standards, it is difficult to estimate the total resources necessary to administer such activities.

Within a few years of enactment, CBO expects that the total costs to administer the new standards for technologists could reach between one-third and one-half of FDA's estimated costs to operate its existing quality assurance program for mammography (excluding costs funded through user fees primarily for activities related to the inspections of facilities). We estimate that implementing S. 2322 would result in additional discretionary outlays of $2 million in 2007 and about $20 million over the 2007-2011 period, assuming the appropriation of the necessary amounts. Although S. 2322 would apply standards to a broader array of technical personnel than does the mammography program, CBO expects that FDA's costs would be lower for the new program because the new standards would apply only to technologists and not to equipment, facilities, or other practitioners as does the mammography program.

Direct Spending

S. 2322 would allow the Secretary of HHS to withhold "federal assistance" from noncompliant providers who participate in health programs under the Secretary's jurisdiction. Vigorous enforcement of educational and credentialing standards for certain technologists under the bill could reduce spending by health programs such as Medicare and Medicaid. Expanding federal standards for such personnel could improve the diagnostic accuracy of imaging tests and reduce the number of images services paid by those programs. However,

based on information provided by CMS, CBO expects that it is unlikely that the Secretary would choose to withhold payments to enforce compliance. Therefore, CBO expects that expanding national standards would not substantially change how Medicare and Medicaid operate, and as a result, probably would not have a significant effect on spending in those programs.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

Although it would add new requirements for individuals who provide medical imaging or radiation therapy services through medical programs that are federally supported, S. 2322 would not preempt state laws that require individuals to be licensed or certified. Consequently, the bill does not contain an intergovernmental mandate as defined in the UMRA. State procedures for licensing or certifying those individuals may be deemed sufficient for meeting the new federal standards. If they are not, states may appeal the decision. Nothing in the bill would require states to implement higher standards in their own law, but in order for individuals to be qualified to act as medical imaging or radiation therapy personnel in most cases, they would have to meet the new federal standards as well—possibly through an accredited nonprofit organization.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 2322 also contains no private-sector mandates as defined in UMRA. The Secretary of the Department of Health and Human Services would be given authority to enforce the requirements of S. 2322 by withholding federal assistance. The requirements created are considered conditions of participation, because they are only enforceable under government programs in which participation is voluntary.

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